

U.S. Consumer Product Safety Commission

MEETING LOG

PRODUCT: Nanotechnology

SUBJECT: ISO/TC 229 Nanotechnologies Working Group Virtual Meetings to Discuss Current Projects and Potential New Work Item Proposals (NWIPs)

LOCATION: Teleconference

DATE: November 8-19, 2021

LOG ENTRY SOURCE: Joanna Matheson (HSTR)

COMMISSION ATTENDEES: Treye Thomas (EXHR), Isaac Mireku (LS), Priscilla Verdino (LS), Joanna Matheson (HSTR)

NON-COMMISSION ATTENDEES: Contact ANSI for a complete list.

MEETING SUMMARY:

ISO Technical Committee 229 (ISO TC/229) focuses on standardization in the field of nanotechnologies, understanding and control of matter and processes at the nanoscale where the onset of size-dependent phenomena usually enables novel applications, as well as use of nanoscale materials to create improved materials, devices, and systems that exploit these new properties. Specific working groups address the development of standards and guides for terminology and nomenclature; metrology and instrumentation; test methodologies; modelling and simulations; and science-based health, safety, and environmental practices.

On Monday November 8, 2021, the general meeting of Working Group 3 (WG3, Health Safety and the Environment) was held during which project leaders, including Treye Thomas, provided brief verbal updates on their respective work and their goals for the targeted project meetings that will occur on November 9-19th. ISO TC/229 encourages proposals for new work items; presentations were given on three proposed projects, including one from Korea on *Toxicity assessment of manufactured nanomaterials in soils using plant Arabidopsis thaliana*, and three from Iran, *Assessment of Protein and Glycoprotein Structural Stability Exposed to Nanoparticles by Mass Spectrometry*; *Nano Emulsions Containing mRNA Used in Medical Applications*; and, *Bio-conjugated Gold Nano-suspensions Characteristics and Measurement Methods*. No OECD update was provided on its nanomaterial test guideline and guidance document program; however the CEN liaison provided a brief update on CEN TC352 and TC137 new activities, including work on a guide on how to measure nanomaterials, the development of sensors to measure airborne nanomaterials in the workplace, and guidance on the determination of agglomeration and aggregation in nano objects. In addition, a survey will be conducted with WG3 experts to consider proposing a project relative to waste management of nanomaterials, building on CEN/TS 17275 project *Guidelines for the management and disposal of waste from the manufacturing and processing of manufactured nano-objects*.

From Tuesday November 9, 2021 through Friday, November 19, 2021, CPSC staff participated primarily in WG3 meetings.

The inaugural meeting was held to revise ISO/TR 13329 *Safety data sheets for nanomaterials*, the only international standard that provides guidance on writing safety data sheets for nanomaterials. Comments were received from seven countries, including that the update should reflect newer standards; terminology and/or definitions of nanoform, signal word, precautionary statement, and primary particle should be added; and language included on consideration of pyrophoric hazards as well as additional physical-chemical characteristics such as bulk and specific density. An inaugural meeting was also held on ISO/TS 7833 *Extraction method of nanomaterials from organs by the proteinase K digestion*. The draft document was reviewed and an issue raised regarding unpublished data in Annex A. The WG3 congener noted that as long as the data is from the project leader's laboratory, it can be included in the standard's text. Additional comments were made that digestion varies in an organ-specific nature. The project leader also provided the nanomaterials assessed with the protocols, which included carbon nanotubes and nanofibers, carbon black, graphene, and graphene oxide. Metal oxide nanomaterials dissolve during the extraction process, so this method would not be appropriate for them, as well as any PEG-coated nanomaterial. Additional experiments will be performed to ensure the clarity of the protocols.

The project leader for ISO 19337 *Characteristics of working suspensions of nano-objects for in vitro assays to evaluate inherent nano-object toxicity*, discussed comments received on the most recent draft document and the resultant updates to the document, including adding sections on contamination, both biological and chemical contamination.

Multiple preliminary work items are in different stages of development, including ISO PWI 4962 *In vitro nanoparticle phototoxicity assay*. The updated draft was distributed for review and comment reflecting the completed inter-laboratory study data (including statistical analysis) on TiO₂ nanopowders. The meeting participants supported this project moving forward as a new work item. ISO PWI 7666 *Evaluation method for chronic inhalation toxicity based on lung burden of nanomaterials* is another preliminary work item that meeting attendees supported its movement forward as a new work item once the suggested changes to the scope were completed. The request was to restrict the scope to insoluble materials. Furthermore, some additional sentences on whether carbon nanotubes and nanofibers translocate outside of the lung, as well as ranges of diameters and lengths of the nanomaterials assessed is added.

For ISO PWI 4963 *Radiotelemetry-spectral-echocardiography based real-time surveillance protocol for in vivo toxicity detection and monitoring of engineered nanomaterials* (ENM), comments received recommended to clarify the scope to indicate it is for ENM and for cardiovascular system-related adverse health effects. Furthermore, the test report section should include information on assessment of long-term effects. Other updates recommended by meeting participants included the addition of existing cardiovascular system standards. CPSC staff monitor this project since this technique was used in the NIOSH interagency agreement studies on laser printer-emitted nanoparticles. An updated draft was reviewed and additional changes suggested for ISO/TS 5094 *Assessment of peroxidase-like activity of metal and metal oxide nanoparticles*. It was suggested to give a description and/or definition of peroxidase reaction in Clauses 3 and 4, and that the IUPAC definition might be of use. It was noted that an appropriate control was needed for this technique, as well as citation added that deionized water was the typical solvent used. Lastly it was discussed that precision measurements and potential sources of uncertainty needed to be added or adjusted in the Measurement Flowchart section. The meeting attendees indicated another round of commenting was preferred before submitting the draft document to ballot. For ISO/TR 5387 *Lung burden measurement of nanomaterials for inhalation toxicity studies*, the project leaders reviewed and resolved comments. Some questions were raised during the meeting regarding clarification of the title and scope; these

will be resolved during the next project meeting in 2022. The CPSC proposed preliminary work item ISO PWI 5265 *Method for characterizing and quantifying nanomaterials released from wood products* was discussed on November 9, 2021. The project leader, Treye Thomas, reviewed the inputs received on the WG3 Survey of Wood Sampling Methods. Five responses were received. Meeting attendees were interested in responding to the survey, therefore it was recommended to relaunch the survey for additional feedback. Questions were answered by CPSC and EPA staff regarding detection limits (they are low in the ppb level with ICP-MS) and whether the treated wood was coated or was permeated with the nanomaterials (both occurred). It was suggested to include the concept of Safety-By-Design in the document since the CPSC and EPA interagency project assessed lifecycle exposure. Additional research was proposed, including broadening the method for other surfaces and on how other solvents may impact nanomaterial release. The WG3 congener cautioned that there should not be a push at the preliminary work item stage for more research.

WG3 held a joint meeting with Working Group 5 (WG5, Products and Applications) on November 17, 2021, to hear updates on TR 23652 *Performance evaluation of radiolabeling methods for nanomaterials*. The project had experienced difficulty in recruiting countries to participate in the project (typically five or more are needed). Participating countries will help complete sections missing in the TR as well as edit the language. Five types of radiolabeling methods are covered in the TR; the project leader believes pros and cons of each method should be added to the TR, likely in an annex. The joint meeting also discussed potential PWI *Nanoparticles Performance of Cellular Uptake*. A similar project existed several years ago, but was terminated. Meeting participants discussed changing the title and scope for this PWI.

Staff are particularly interested in a project proposed for the detection of nano-objects released from respiratory masks/media. The presenters noted that due to the SARS-CoV2 pandemic, greater attention is on the types of materials used in masks (including nanomaterials such as graphene, carbon nanotubes, and nano silver) and concern regarding the potential release of these materials and their impact on human health. No update was given at the November 2021 meetings, but is expected in 2022. Staff will continue to monitor the development of this project.